

Applicant : Eric M. DoBrava et al.
Serial No. : 10/044,277
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Attorney's Docket No.: 10527-434001 / 00-0300

REMARKS

In the Office Action, claims 1-18 are pending, claims 19-22 are withdrawn, claims 23-25 are new, and claims 1-18 stand rejected. Of the rejected claims, claim 1 is the only independent claim.

Claims 1, 2, 5-7, 13-15, and 17-18 have been amended in this response.

Rejection Under 35 U.S.C. § 102(b) Over Adams

Claims 1-2 and 18 stand rejected under 35 U.S.C. § 102(b) over U.S. Patent 5,527,292 to Adams et al. ("Adams"). Claim 1 is the independent claim in the group.

Claim 1 as amended recites a catheter for removing core material from a plaque deposit on an inside wall of a blood vessel. The catheter comprises a radially extendible collection array having one or more collection lumens to receive core material at the periphery of the blood vessel.

Adams simply discusses a general purpose "intravascular device suited for use during angioplasty treatment." See Adams, col. 2, lines 37-38. The intravascular device includes a flexible tube (255), a lumen (269), a distal extension (250), and a proximal funnel (260). See *id.*, col 14, lines 1-2, 14-17; col. 16, lines 12-16. The proximal funnel "serves to direct an angioplasty device into the lumen 269 of the extension 250, or to provide a distal extension of the lumen of the guide catheter for fluid delivery." See *id.* col. 16, lines 12-16.

Adams is different from the claimed inventions. First, Adams lacks a collection array. As described above, what the Examiner refers to as a collection array (260) is in actuality a funnel to guide devices inside the lumen. Second, even if the proximal funnel is construed to be a collection array, it is *not radially extendible*. Adams neither discloses nor fairly suggests the inventions in claim 1 and its dependent claims. As a result, Applicants respectfully request withdrawal of the rejection based on Adams.

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Rejection Under 35 U.S.C. § 102(e) Over Peacock III

Claims 1 and 3-17 stand rejected under 35 U.S.C. § 102(e) over U.S. Patent 6,234,995 to Peacock III ("Peacock"). Claim 1 is the independent claim in the group.

Claim 1 as amended recites a catheter for removing core material from a plaque deposit on an inside wall of a blood vessel. The catheter comprises a radially extendible collection array having one or more collection lumens to receive core material at the periphery of the blood vessel.

Peacock discusses a catheter that is adapted for use in a minimally invasive cardiac bypass system. *See* Peacock col. 9, line 66 to col. 10, line 5; FIG. 11. The catheter includes an elongate body (41); a series of lumens, including an internal flow lumen (43'); a distal flow port (68) and an intermediate flow port (66), each of which include a plurality of apertures; an external shunt valve (70); an external shunt valve actuating lumen (46); a distal internal valve (64); and a distal internal valve actuating lumen (44). *See id.* col. 18, line 20 to col. 19, line 6. In an expanded condition, the external shunt valve (70) forms an anchor (71) and a funnel (72). *See id.* col. 19, lines 7-10.

In Peacock, these elements interoperate to either allow blood flow between various portions of the catheter system or to isolate portions of the catheter and corresponding portions of vascular structure during a bypass procedure. Various modes of operation facilitated by the interoperation of these elements are described with reference to FIGs. 12 and 13. For example, when the external shunt (303) valve is expanded, blood is directed "into distal flow port (306), proximally through an internal flow lumen (not shown) and out an intermediate flow port (307)." *See id.* col. 33, lines 43-52. This allows the heart to continue beating while allowing systemic arterial circulation. *See id.* col. 33, lines 56-57; FIG. 12. In another mode, "[w]ith the external shunt valve (303) still anchored in the aortic arch in a shunting position, the internal lumen is selectively occluded with a distal internal valve (not shown) within the internal lumen between the distal and intermediate flow ports (306 and 307) according to the operable mode shown in FIG. 13." *See id.* col. 34, lines 33-38; FIG. 13. In this mode, the left heart chambers are isolated

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from systemic arterial circulation, while blood flows artificially through the internal lumen from a cardiopulmonary bypass pump. *See id.* col. 34, lines 38-45.

Peacock is different from the claimed inventions. First, the Peacock device is not useful for removing core material from a plaque deposit on an inside wall of a blood vessel; rather, the Peacock device is specifically adapted to support minimally invasive bypass procedures. Second, even if the Peacock device were used to remove core material from a plaque deposit, it *lacks a radially extendible collection array* having one or more collection lumens to receive core material at the periphery of a blood vessel. What the Examiner refers to as a collection array (70, 303) is in actuality an external shunt valve. It does not itself include one or more collection lumens to receive core material at the periphery of the blood vessel. In some modes of operation, the external shunt valve (70, 303) directs blood into the distal flow port (306), but *the distal flow port does not itself expand radially to receive core material at the periphery of the blood vessel.*

By expanding radially, the claimed collection array gives rise to significant advantages not present in the device described in Peacock. Specifically, the claimed collection array can be expanded to contact and subsequently rupture a plaque deposit. The one or more collection lumens can then remove the ruptured core material of the plaque deposit *at the periphery of the blood vessel*—the site of the plaque deposit—reducing the likelihood that core material will escape from the treatment site, and further reducing the likelihood that a thrombus will form.

Peacock is simply aimed at an entirely different purpose than the claimed inventions—supporting a minimally invasive cardiac bypass procedure rather than extracting core material from plaque deposits. It neither discloses nor fairly suggests the inventions in claim 1 and its dependent claims. As a result, Applicants respectfully requests withdrawal of the rejection based on Peacock.

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New Claims

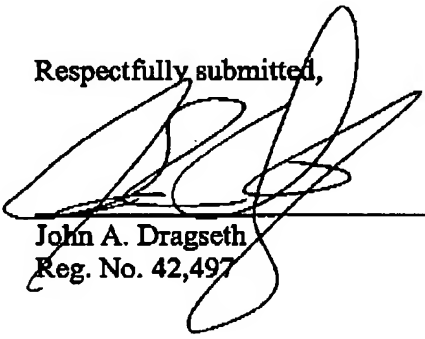
New claims 23-25 have support in the application as originally filed, including at page 6, line 20 to page 7, line 2; page 9, lines 1-3; page 10, lines 5-8; and in Figures 3 and 4. The claims are believed to be clearly allowable over the art of record. No new matter has been added.

For the foregoing reasons, Applicants respectfully suggest that the claims are in condition for immediate allowance.

This amendment is being filed concurrently with a Request for Continued Examination. Please charge the requisite fees of \$790 for the Request for Continued Examination, and \$120 for the Petition for Extension of Time to Deposit Account No. 06-1050. Please apply any other charges or credits to deposit account 06-1050.

Date: 7-5-05

Respectfully submitted,


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